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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/076,907	02/13/2002	Joel S. Douglas	032994-050	1881
7590 10/20/2004			EXAMINER	
T. Gene Dillahunty BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			MAIORINO, ROZ	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/076,907

Applicant(s)

DOUGLAS ET AL.

Examiner

Roz Maiorino

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims s 1-5, 7, 11—21 are rejected under 35 U.S.C. 102(e) as being anticipated by US Paten NO. 6361523 to Bierman.

Bierman teaches an infusion system with a housing 20 having a general flat bottom and a connecting hub110, the connecting hub having an internal Y-shaped flow channel structure. The flow channels comprises of a first flow channel connected to a proximal end of infusion cannula and exit the distal end of the hub, a second flow channel exit form proximal end of the hub and a third flow channel exit form a proximal end of the hub. An infusion cannula may be received in the distal end of the housing. The connecting hub is attached to the proximal end of a housing via fasteners. The channel in housing is tapered (as demonstrated by figure 6 the channel is tapered at the distal end, also see figures 6, 12-13, 21)

Art Unit: 3763

2. Claims 1-5, 7-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Paten No.4755173 to Konopka et al

Konopka teaches an infusion system with a housing 412 having a general flat bottom and a connecting hub, the connecting hub having an internal Y-shaped flow channel structure. The flow channels comprises of a first flow channel connected to a proximal end of infusion cannula and exit the distal end of the hub, a second flow channel exit form proximal end of the hub and a third flow channel exit form a proximal end of the hub. An infusion cannula may be received in the distal end of the housing. The connecting hub is attached to the proximal end of a housing via fasteners. The channel in housing is tapered (see figure 11).

3. Claims 1-5, 7-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Paten No.5839715 to Leinsing or US Patent No. 4735614 to Yapp et al

Both Leinsing and Yapp teach an infusion system with a housing having a general flat bottom and a connecting hub, the connecting hub having an internal Y-shaped flow channel structure. The flow channels comprises of a first flow channel connected to a proximal end of infusion cannula and exit the distal end of the hub, a second flow channel exit form proximal end of the hub and a third flow channel exit form a proximal end of the hub. An infusion cannula may be received in the distal end of the housing. The connecting hub is attached to the proximal end of a housing via fasteners. The channel in housing is tapered.

4. Claims 1-5, 7-21 are rejected under 35 U.S.C. 102(e) as being anticipated by US Paten No.6228062 to Howell et al.

Art Unit: 3763

Howell teaches an infusion system with a housing having a general flat bottom and a connecting hub, the connecting hub having an internal Y-shaped flow channel structure. The flow channels comprises of a first flow channel connected to a proximal end of infusion cannula and exit the distal end of the hub, a second flow channel exit form proximal end of the hub and a third flow channel exit form a proximal end of the hub. An infusion cannula may be received in the distal end of the housing. The connecting hub is attached to the proximal end of a housing via fasteners. The channel in housing is tapered.

### ***Response to Arguments***

Applicant's arguments filed 7-9/2004 have been fully considered but they are not persuasive.

- a. In response to applicant's argument that Bierman nor Konopka disclose any means to infuse anything in the body, a recitation of the intended use/functional language of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Art Unit: 3763

b. Furthermore the applicant alleges the definition of catheter and cannula are Not the same. However that is incorrect, according to the dictionary both are described as "a tube for insertion into a body cavity or duct or vessel". If the applicant wants to limit the definition of cannula to mean needle he should claim a needle and not a cannula.

c. Applicant's arguments with respect to claims 1-5, 7-21 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

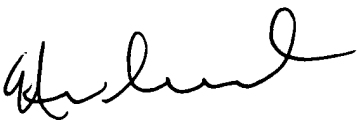
Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 703-305-2336. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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